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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,361	12/21/2001	Kevin McGrath	1443.025US1	5006
21186	7590	09/28/2005		
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH P.O. BOX 2938 MINNEAPOLIS, MN 55402-0938			EXAMINER LIU, SAMUEL W	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 09/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/032,361

Applicant(s)

MCGRATH, KEVIN

Examiner

Samuel W. Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2 and 25-49 is/are pending in the application.
- 4a) Of the above claim(s) 30-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2 and 25-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of the claims

Claims 2 and 25-49 are pending.

The amendment filed 6/16/05, which cancels claims 1, 3-15 and 17-24 and 50-52, and amends claims 25-29 has been entered. Note that claim 8 and 16 are canceled by applicants' amendment filed 1/4/05. Claims 30-49 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention (see Office action mailed 9/3/04). Thus, the pending claims 2 and 25-29 are examined in this office action.

Please note that ground of objection and/or rejection not explicitly restated and/or set forth below are withdrawn.

Election/restriction

In response to the applicants' question with regard to status of the previously pending claims 43-49 (drawn to non-elected invention), the claims should be drawn to Group II method (see the restriction requirement mailed 5/26/05).

Objection to claim

The disclosure is objected to because of the following informalities:

In claim 25, "an amino acid sequence SEQ ID NO:7" should be changed to "an amino acid sequence of SEQ ID NO:7".

Appropriate correction is required.

Claim Rejections - 35 USC § 112, the first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with

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which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2 and 25-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are drawn to an isolated peptide (claim 2) and a pharmaceutical composition comprising a peptide comprising SEQ ID NO:7 (claim 25) or SEQ ID NO:4 (claim 26) sequence. Claim 2 as written does not set forth biological function of the claimed; and thus, one skilled in the art cannot recognize when they are in possession of the claimed peptide having assayable activity. The specification does not teach active peptide or polypeptide comprising the sequence, e.g., SEQ ID NO:4 (claim 26). Also, claims 25-26 as written are drawn to a peptide fragment (see the limitation "*an amino acid sequence of SEQ ID NO:7*"). Therefore, the specification lacks written description for these claim limitations.

Appellants may wish to amend the claims to additionally list a specific, measurable activity or function (e.g., regulating hypoxia inducible factor-1 activity) that these variables must have so that one skilled in the art can recognize when they are in possession of the claimed peptide (but not the fragment thereof) and the claimed pharmaceutical composition comprising the peptide thereof.

The current invention is directed to the composition comprising the peptide comprising SEQ ID NO:4 or 7 to inhibit ubiquitination of hypoxia inducible factor 1 alpha (HIP-1 α) and activate transcription of erythropoietin (EPO) and vascular endothelial growth factor (VEGF) (see page 2 of the specification). The specification, however, does not teach a protein (e.g., a

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protein consisting of 1,000 amino acid residues) comprising the instant SEQ ID NO:4 (eight residues) still has inhibitory activity of inhibiting ubiquitination as the peptide consisting of the SEQ ID NO:4 sequence. In light of that the 8-residues peptide of SEQ ID NO:4 can reside (be concealed) within the folded protein thereof which results in inactive inhibition of the ubiquitination. Therefore, one skilled in the art is not in possession of the claimed composition.

Since the written description must therefore communicate that which is necessary to enable the skilled artisan to make and use the claimed invention, the current invention need to fulfill the written description requirement stated above. A description that does not meet this requirement is legally insufficient (see *Kennecott Corp. v. Kyocera Int'l, Inc.*, [835 F.2d 1419] 835 F.2d 1419, 5 USPQ2d 1194 (Fed. Cir. 1987)).

Claim Rejections - 35 USC § 112, the second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 25-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 is not apparent in “an amino acid sequence SEQ ID NO:7” because is “an amino acid sequence” is considered to be a fragment; does the claim is directed to a peptide comprising the amino acid sequence of SEQ ID NO:7 and/or the fragment thereof? The dependent claims are also rejected.

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Claim 26 recites "consisting essentially of"; the recitation is not apparent as to what is the meaning of "essentially" herein? Is this claim language equal to or not equal to "comprising"? The dependent claims are also rejected.

In light of the prior art does not teach the peptide of SEQ ID NO:4 or SEQ ID NO:7 and/or the pharmaceutical composition comprising the peptide thereof, the rejections under 35 USC 102 and 103 in the Office action mailed 3/11/05 are withdrawn.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

swl

Samuel Wei Liu, Ph.D.
Art Unit 1653, Examiner
September 21, 2005



JON WEBER
SUPERVISORY PATENT EXAMINER